



PATENT
Serial No. 10/693,377

PTO-1449 (Modified)	Attorney Docket No.: TLAB.100292	Serial Number: 10/693,377
U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE		
INFORMATION DISCLOSURE STATEMENT BY APPLICANT		
Applicant: James Hunter Boone, et al.		
Title: INFLAMMATORY BOWEL DISEASE AND IRRITABLE BOWEL SYNDROME IBD- FIRST CHEK DIAGNOSTIC PANEL	Filing Date: October 24, 2003	Group:

U.S. PATENT DOCUMENTS

EXAMINER INITIAL	PATENT NUMBER	ISSUE DATE	INVENTOR	CLASS	SUBCLASS	FILING DATE
GP	5,124,252	June 23, 1992	Guerrant, et al.			
GP	5,359,038	October 25, 1994	Padron, Eloy			
GP	5,455,160	October 3, 1995	Fagerhol, et al.			
GP	5,552,292	September 3, 1996	Uchida, et al.			
GP	5,932,429	August 3, 1999	Targan, et al.			
GP	5,968,741	October 19, 1999	Plevy, et al.			
GP	6,008,335	December 28, 1999	Rotter, et al.			
GP	6,218,129	April 17, 2001	Walsh, et al.			

OTHER DOCUMENTS (Including Author, Title, Date, Relevant Pages, Place of Publication)

GP	R. Barnes, S. Allan, C. Taylor-Robinson, R. Finn, P. Johnson, "Serum Antibodies Reactive with <i>Saccharomyces cerevisiae</i> in Inflammatory Bowel Disease: Is IgA Antibody a Marker for Crohn's Disease?" <i>Int Arch Allergy Appl Immunol</i> (1990) 92, 9-15.
GP	C. Faille, D. Mackenzie, J. Michalski, and D. Poulain, "Evaluation of an Enzyme Immunoassay Using Neoglycolipids Constructed from <i>Candida albicans</i> Oligomannosides to Define the Specificity of Anti-Mannan Antibodies" <i>Eur. J. Clin. Microbiol. Infect. Dis.</i> , (1992) May, 438-446.
GP	M. Giaffer and C. Holdsworth, "Antibodies to <i>Saccharomyces cerevisiae</i> in patients with Crohn's disease and their possible pathogenic importance" <i>Gut</i> (1992) 33, 1071-1075.

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FOREIGN PATENT OR PUBLISHED FOREIGN PATENT APPLICATION:

EXAMINER INITIAL	DOCUMENT NUMBER	PUBLICATION DATE	COUNTRY OR PATENT OFFICE	CLASS	SUBCLASS
GP	WO 02/39883 A2 (TECHLAB, INC.)	23 May 2002	PCT	A61B	
GP	WO 01/36975 A1 (BINAX, INC.)	25 May 2001	PCT	G01N 33/553, 33/543	
GP	WO 92/16843 A1 (GUERRANT, R.L. et al.)	01 October 1992	PCT	G01N 33/545, 33/546	

OTHER DOCUMENTS (Including Author, Title, Relevant Pages, and Place of Publication, Date)

GP	VERMEIRE, S. et al. Comparative Study of ASCA (Anti_Saccharomyces cerevisiae Antibody) Assays in Inflammatory Bowel Disease. Gastroenterology. 2001, Vol. 120, pages 827-833, see Materials and Methods all sections, and entire document.
GP	DUBINSKY, M.C. et al. Clinical Utility of Serodiagnostic Testing in Suspected Pediatric Inflammatory Bowel Disease. American Journal of Gastroenterology (United States). March 2001, Vol. 96, No. 3, pages 758-765, especially abstract "the combination of these serodiagnostic test could maximize diagnostic accuracy and minimize invasive investigations," and entire document.
GP	BOONE, J. H. et al. Measurement of Anti-Saccharomyces cerevisiae antibodies in human feces as an indicator of Crohn's disease. American Journal of Gastroenterology. September 2002, Vol. 97, No. 9, page S253 (Abstract only).

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01/08/2007

The Commissioner is hereby authorized to charge any additional fees that are required, or credit any overpayment, to Deposit Account No. 19-2112.

Respectfully submitted,

Jean M. Dickman

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Serial No. 10/693,377

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Attorney Docket No. TLAB.100292



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GP	C. Young, A. Sonnenberg, and E. Burns, "Lymphocyte Proliferation Response to Baker's Yeast in Crohn's Disease" <i>Digestion</i> (1994) 55, 40-43.
GP	M. Gjafer, A. Clark, C. Holdsworth, "Antibodies against <i>Saccharomyces Cerevisiae</i> (Baker's & Brewer's yeast) in Crohn's Disease" <i>Gastroenterology</i> (1991) 100, No. 5, Part 2.
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GP	N. Oshitani, et al., <u>IgG subclasses of anti <i>Saccharomyces cerevisiae</i> antibody in inflammatory bowel disease</u> ; Blackwell-Science Ltd., European Journal of Clinical Investigation, Vol. 31, pp.221-225,2001.
GP	Trulove SC, Witts LJ. Cortisone in Ulcerative Colities. Final Report on a Therapeutic Trial. British Medical Journal 1955; 4947:1041-1048.
GP	Baveye, S., Ellass, E., Mazurier, J., Spik, G., Legrand, D. Lactoferrine: a Multifunctional Glycoprotein Involved in the Modulation of the Inflammatory Response. Clin. Chem. Lab Med. 1999; 37(3):281-86.
GP	Suleiman S, Sonnenberg A. Cost-effectiveness of Endoscopy in Irritable Bowel Syndrome. Arch Intern Med 2001; 161:369-75.
GP	Levay, PF and Viljoen, J. Lactoferrin: a General Review. Haematologica. 1995; 80(3):256-67.
GP	Roseth AG, Aadland E, Jahnsen J, Raknerud N. Assessment of Disease Activity in Ulcerative Colitis by Faecal Calprotectin, a Novel Granulocyte Marker Protein. Digestion 1997; 58:176-80.
GP	Lagerholm S., Dutta SK, Merchant, NB, Nair, PP. COX-2 Expression in Fecal Colonocytes from Patients with Inflammatory Bowel Disease. Gastro 2001; 120:A16.



OTHER DOCUMENTS (Including Author, Title, Date, Relevant Pages, Place of Publication)

GP	Hammer J., Talley NJ. Diagnostic Criteria for the Irritable Bowel Syndrome. Am. J. Med. 1999; 107:5S-11S.
	Limburg, P.L., Ahlquist, D.A., Sandborn, W., et al. Fecal Calprotectin Levels Predict Colorectal Inflammation among Patients with Chronic Diarrhea Referred for Colonoscopy. Amer. J. of Gastro. 2000; 95:2831-2837.
	Steiner TS, Flores CA, Pizarro TT, Guerrant RL. Fecal Lactoferrin, Interleukin-1 Beta, and Interleukin-8 Are Elevated in Patients with Severe Clostridium Difficile Colitis. Clin Diagn Lab Immunol 1997; 4:719-22.
	Naidu, A., Satyanarayan and Roland R. Arnold 1997. Influence of Lactoferrin on Host-Microbe Interactions. In T. William Hutchens and Bo Lonnerdal (ed.), Lactoferrin, pp. 259-275. Humana Press.
	Andus T., Gross V., Caesar I, et al. PMN-elastase in Assessment of Patients with Inflammatory Bowel Disease. Dig. Dis. Sci. 1993; 35:97-105.
	Tibble JA, Sigthorsson G, Bridger S, Fagerhol MK, Bjarnason I. Surrogate Markers of Intestinal Inflammation Are Predictive of Relapse in Patients with Inflammatory Bowel Disease. Gastroenterology 2000; 119:15-22.
	Dwarakanath, AD, Finnie, IA, Beesley, C M, et al. Differential Excretion of Leukocyte Granule Components in Inflammatory Bowel Disease: Implications for Pathogenesis. Clin. Sci. 1997; 92:307-313.
	Riley, L.W. 1995. Acute Inflammatory Diarrhea. In M. Blaser (ed.), P. Smith, J. Ravdin, H. Greenberg, and R. Guerrant, <u>Infections of the Gastrointestinal Tract</u> . Raven Press, New York, NY.
	Tauxe, R., and M. Cohen. 1995. Epidemiology of Diarrheal Diseases in Developed Countries. In M. Blaser, P. Smith, J. Ravdin, H. Greenberg, and R. Guerrant (ed.), <u>Infections of the Gastrointestinal Tract</u> . Raven Press, New York, NY.
↓	Sartor, R.B. 1995. Microbial Agents in Pathogenesis, Differential Diagnosis, and Complications of Inflammatory Bowel Disease. In M. Blaser, P. Smith, J. Ravdin, H. Greenberg, and R. Guerrant (ed.), <u>Infections of the Gastrointestinal Tract</u> . Raven Press, New York, NY.
GP	Mathias, JR, Clench, MH, Reeves-Darby, VG, et al. Effect of Leuprolide Acetate in Patients with Moderate to Severe Functional Bowel Disease: Double-Blind, Placebo-Controlled Study. Dig Dis Sci, 1994; 39(6):1155-62.



OTHER DOCUMENTS (Including Author, Title, Date, Relevant Pages, Place of Publication)

GP	Uchida, K., R. Matsuse, S. Tomita, K. Sugi, O. Saitoh, and S. Ohshiba. 1994. Immunochemical Detection of Human Lactoferrin in Feces as a New Marker for Inflammatory Gastrointestinal Disorders and Colon Cancer. Clin. Biochem. 27:259-264.
	Sugi, K., Saitoh, O., Hirata, I., and K. Katsu. 1996. Fecal Lactoferrin as a Marker for Disease Activity in Inflammatory Bowel Disease: Comparison with Other Neutrophil-derived Proteins. Amer. J. Gastroenterol. 91:927-934.
	Guerrant, R.L., V. Araujo, E. Soares, K. Kotloff, A. Lima, W. Cooper, and A. Lee. 1992. Measurement of Fecal Lactoferrin as a Marker of Fecal Leukocytes. J. Clin. Microbiol. 30:1238-1242.
	Fine, K.D., F. Ogunji, J. George, M. Niehaus, and R. Guerrant. 1998. Utility of a Rapid Fecal Latex Agglutination Test Detecting the Neutrophil Protein, Lactoferrin, for Diagnosing Inflammatory Causes of Chronic Diarrhea. Amer. J. Gastroenterol. 93:1300-1305.
	Camilleri, M. 2001. Management of Irritable Bowel Syndrome. Gastroenterol. 120:652-668.
	Calkins, Beverly M., Everhart, J.E. Ed 1994. Inflammatory Bowel Diseases, Digestive Diseases in the United States: Epidemiology and Impact., Chapter 16, pgs. 509-550 U.S. Department of Health and Human Services, National Institute of Health, National Institute of Diabetes and Digestive and Kidney Diseases. U.S. Government Printing Office, NIH Publication No. 94-1447.
	Sandler, Robert, Everhart, J.E. 1994. Irritable Bowel Syndrome, Digestive Diseases in the United States: Epidemiology and Impact., Chapter 19, pgs. 596-612, U.S. Department of Health and Human Services, National Institute of Health, National Institute of Diabetes and Digestive and Kidney Diseases. U.S. Government Printing Office, NIH Publication No. 94-1447.
	Harris, J.C., H.L. DuPont, and B.R. Hornick. 1971. Fecal Leukocytes in Diarrheal Illness. Ann. Intern. Med. 76:697-703.
	Pool, et al. "Serum antineutrophil cytoplasmic autoantibodies in inflammatory bowel disease....." Gut, 1993, 46-50.
	Peen, et al. "Distribution of lactoferrin and 60/65kDa heat shock protein in normal and inflamed human intestine and liver." Gut, 1996, 38, 135-140.
GP	Peen, et al. "Anti-lactoferrin antibodies and other types of ANCA in ulcerative colitis, primary sclerosing cholangitis, and Crohn's disease. Gut, 1993, 34, 56-62.



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FOREIGN PATENT OR PUBLISHED FOREIGN PATENT APPLICATION

EXAMINER INITIAL	DOCUMENT NUMBER	PUBLICATION DATE	COUNTRY OR PATENT OFFICE	CLASS	SUBCLASS	TRANSLATION	
						YES	NO
GP	WO 99/60403	11/25/1999	PCT		G01N 33/564, 33/569		
GP	WO 97/39356	10/23/1997	PCT		G01N 33/564		
GP	WO 98/46997	10/22/1998	PCT		G01N 33/53, C12Q 1/68		
GP	WO 01/11334 A2	02/15/2001	PCT		G01N		
GP							

EXAMINER	/Virginia Portner/	DATE CONSIDERED	01/08/2007
EXAMINER: Initial citation if reference was considered. Draw line through citation if not in conformance to MPEP 609 and not considered. Include copy of this form with next communication to applicant.			



02/06/2004

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

James Hunter Boone, et al.

Serial No. 10/693,377

Filed: October 24, 2003

Title: INFLAMMATORY BOWEL
DISEASE AND IRRITABLE
BOWEL SYNDROME IBD-
FIRST CHEK DIAGNOSTIC
PANEL

Art Unit:

Examiner:

Attorney Docket: TLAB.100292

CERTIFICATE OF MAILING
37 C.F.R. 1.8

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Nancy Morton
Signature

INFORMATION DISCLOSURE STATEMENT

Mail Stop DD
Commissioner for Patents
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Dear Sir:

In compliance with Applicants duty of disclosure pursuant to 37 C.F.R. Section 1.56, it is requested that this Information Disclosure Statement be entered and that the references listed below and on the enclosed Form PTO-1449 be considered by the Examiner and made of record. Copies of the above-referenced documents are enclosed.

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GP	5,124,252	June 23, 1992	Guerrant, et al.
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GP	Truelove SC, Witts LJ. Cortisone in Ulcerative Colitis. Final Report on a Therapeutic Trial. British Medical Journal 1955; 4947:1041-1048.
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GP	Steiner TS, Flores CA, Pizarro TT, Guerrant RL. Fecal Lactoferrin, Interleukin-1 Beta, and Interleukin-8 Are Elevated in Patients with Severe Clostridium Difficile Colitis. Clin Diagn Lab Immunol 1997; 4:719-22.
GP	Naidu, A. Satyanarayan and Roland R. Arnold, 1997. Influence of Lactoferrin on Host-Microbe Interactions. In T. William Hutchens and Bo Lonnerdal (ed.), Lactoferrin, pp. 259-275. Humana Press.
GP	Andus T., Gross V., Caesar I., et al. PMN-elastase in Assessment of Patients with Inflammatory Bowel Disease. Dig. Dis. Sci. 1993; 35:97-105.
GP	Tibble JA, Sigthorsson G, Bridger S, Fagerhol MK, Bjarnason I. Surrogate Markers of Intestinal Inflammation Are Predictive of Relapse in Patients with Inflammatory Bowel Disease. Gastroenterology 2000; 119:15-22.
GP	Dwarakanath, AD, Finnie, IA, Beesley, C M, et al. Differential Excretion of Leukocyte Granule Components in Inflammatory Bowel Disease: Implications for Pathogenesis. Clin. Sci. 1997; 92:307-313.

/Virginia Portner/ 01/08/2007

OTHER DOCUMENTS (Including Author, Title, Relevant Pages, and Place of Publication, Date)

GP	Riley, L.W. 1995. Acute Inflammatory Diarrhea. In M. Blaser (ed.), P. Smith, J. Ravdin, H. Greenberg, and R. Guerrant, <u>Infections of the Gastrointestinal Tract</u> . Raven Press, New York, NY.
GP	Tauxe, R., and M. Cohen. 1995. Epidemiology of Diarrheal Diseases in Developed Countries. In M. Blaser, P. Smith, J. Ravdin, H. Greenberg, and R. Guerrant (ed.), <u>Infections of the Gastrointestinal Tract</u> . Raven Press, New York, NY.
GP	Sartor, R.B. 1995. Microbial Agents in Pathogenesis, Differential Diagnosis, and Complications of Inflammatory Bowel Disease. In M. Blaser, P. Smith, J. Ravdin, H. Greenberg, and R. Guerrant (ed.), <u>Infections of the Gastrointestinal Tract</u> . Raven Press, New York, NY.
GP	Mathias, JR, Clench, MH, Reeves-Darby, VG, et al. Effect of Leuprolide Acetate in Patients with Moderate to Severe Functional Bowel Disease: Double-Blind, Placebo-Controlled Study. <u>Dig Dis Sci</u> , 1994; 39(6):1155-62.
GP	Uchida, K., R. Matsuse, S. Tomita, K. Sugi, O. Saitoh, and S. Ohshiba. 1994. Immunochemical Detection of Human Lactoferrin in Feces as a New Marker for Inflammatory Gastrointestinal Disorders and Colon Cancer. <u>Clin. Biochem.</u> 27:259-264.
GP	Sugi, K., Saitoh, O., Hirata, I., and K. Katsu. 1996. Fecal Lactoferrin as a Marker for Disease Activity in Inflammatory Bowel Disease: Comparison with Other Neutrophil-derived Proteins. <u>Amer. J. Gastroenterol.</u> 91:927-934.
GP	Guerrant, R.L., V. Araujo, E. Soares, K. Kotloff, A. Lima, W. Cooper, and A. Lee. 1992. Measurement of Fecal Lactoferrin as a Marker of Fecal Leukocytes. <u>J. Clin. Microbiol.</u> 30:1238-1242.
GP	Fine, K.D., F. Ogunji, J. George, M. Niehaus, and R. Guerrant. 1998. Utility of a Rapid Fecal Latex Agglutination Test Detecting the Neutrophil Protein, Lactoferrin, for Diagnosing Inflammatory Causes of Chronic Diarrhea. <u>Amer. J. Gastroenterol.</u> 93:1300-1305.
GP	Camilleri, M. 2001. Management of Irritable Bowel Syndrome. <u>Gastroenterol.</u> 120:652-668.
GP	Calkins, Beverly M., Everhart, J.E. 1994. Digestive Diseases in the United States: Epidemiology and Impact., Inflammatory Bowel Diseases, pgs. 509-550 U.S. Department of Health and Human Services, National Institute of Health, National Institute of Diabetes and Digestive and Kidney Diseases. U.S. Government Printing Office, NIH Publication No. 94-1447.
GP	Sandler, Robert, Everhart, J.E. 1994. Digestive Diseases in the United States: Epidemiology and Impact. , Irritable Bowel Syndrome, pgs. 596-612, U.S. Department of Health and Human Services, National Institute of Health, National Institute of Diabetes and Digestive and Kidney Diseases. U.S. Government Printing Office, NIH Publication No. 94-1447.
GP	Harris, J.C., H.L. DuPont, and B.R. Hornick. 1971. Fecal Leukocytes in Diarrheal Illness. <u>Ann. Intern. Med.</u> 76:697-703.

OTHER DOCUMENTS (Including Author, Title, Relevant Pages, and Place of Publication, Date)

Pool, et al. "Serum antineutrophil cytoplasmic autoantibodies in inflammatory bowel disease....."
Gut, 1993, 46-50.

Peen, et al. "Distribution of lactoferrin and 60/65kDa heat shock protein in normal and inflamed human intestine and liver." Gut, 1996, 38, 135-140.

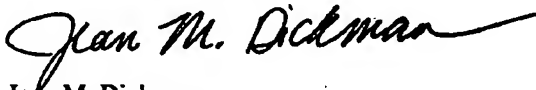
Peen, et al. "Anti-lactoferrin antibodies and other types of ANCA in ulcerative colitis, primary sclerosing cholangitis, and Crohn's disease. Gut, 1993, 34, 56-62.

FOREIGN PATENT OR PUBLISHED FOREIGN PATENT APPLICATION

EXAMINER INITIAL	PUBLICATION NUMBER	PUBLICATION DATE	COUNTRY OR PATENT OFFICE	CLASS	SUBCLASS
GP	WO 99/60403	25 November 1999	PCT	G01N 33/564, 33/569	
GP	WO 97/39356	23 October 1997	PCT	G01N 33/564	
GP	WO 98/46997	22 October 1998	PCT	G01N 33/53, C12Q 1/68	
GP	WO 01/11334 A2	15 February 2001	PCT	G01N	

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Respectfully submitted,



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Attorney Docket No. TLAB.100292



PTO - 1449 (Modified) U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE INFORMATION DISCLOSURE STATEMENT BY APPLICANT	Attorney Docket No.: TLAB.100292	Serial Number: 10/693,377
	Applicant: James Hunter Boone; David Maxwell Lyerly; Tracy Dale Wilkins	
	Filing Date: October 24, 2003	Group:

U.S. PATENT DOCUMENTS

EXAMINER INITIAL	PATENT NUMBER	PUBLICATION NO	ISSUE DATE	INVENTOR	CLASS	SUB- CLASS	FILING DATE

FOREIGN PATENT OR PUBLISHED FOREIGN PATENT APPLICATION

EXAMINER INITIAL	DOCUMENT NUMBER	PUBLICATION DATE	COUNTRY OR PATENT OFFICE	CLASS	SUBCLASS
GP	WO 02/39883 A2 (TECHLAB, INC.)	23 May 2002	PCT	A61B	
GP	WO 01/36975 A1 (BINAX, INC.)	25 May 2001	PCT	G01N 33/553,33/543	
GP	WO 92/16843 A1 (GUERRANT, R.L. et al.)	01 October 1992	PCT	G01N 33/545, 33/546	

/Virginia Portner/

01/08/2007

OTHER DOCUMENTS (Including Author, Title, Date, Relevant Pages, Place of Publication)

GP	VERMEIRE, S. et al. Comparative Study of ASCA (Anti-Saccharomyces cerevisiae Antibody) Assays in Inflammatory Bowel Disease. Gastroenterology. 2001, Vol. 120, pages 827-833, see Materials and Methods all sections, and entire document.		
GP	DUBINSKY, M.C. et al. Clinical Utility of Serodiagnostic Testing in Suspected Pediatric Inflammatory Bowel Disease. American Journal of Gastroenterology (United States). March 2001, Vol. 96, No. 3, pages 758-765, especially abstract "the combination of these serodiagnostic test could maximize diagnostic accuracy and minimize invasive investigations," and entire document.		
GP	BOONE, J. F. et al. Measurement of Anti-Saccharomyces cerevisiae antibodies in human feces as an indicator of Crohn's disease. American Journal of Gastroenterology. September 2002, Vol. 97, No. 9, page S253 (Abstract only).		
EXAMINER	/Virginia Portner/	DATE CONSIDERED	01/08/2007
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)	Application Number		09981248 10/693,377 187
	Filing Date		2001-10-16
	First Named Inventor	James Hunter Boone	
	Art Unit	1645	
	Examiner Name		
	Attorney Docket Number	TLAB.100292	

GP	1	KAZUO UCHIDA, et al., Immunochemical Detection of Human Lactoferrin in Feces as a New Marker for Inflammatory Gastrointestinal Disorders and Colon Cancer, Clinical Biochemistry, Vol. 27, No. 4, pp. 259-264, 1994, The Canadian Society of Clinical Chemists.	<input type="checkbox"/>
GP	2	OSAMU SAITOH, M.D., et al., Fecal Eosinophil Granule-Derived Proteins Reflect Disease Activity in Inflammatory Bowel Disease, The American Journal of Gastroenterology, Vol. 94, No. 12, 1999	<input type="checkbox"/>

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